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REMARKS

Claims 1-4 and 6-14 are pending in the application. Claim 1 is the only independent claim.

Claims 1-4 and 6-11 were rejected under 35 USC 103(a) as being unpatentable over US Patent 5,868,735 (Lafontaine) in view of US Patent 5,106,360 (Ishiwara et al.) and further in view of US Patent 4,445,892 (Hussein et al.). Claim 12 was rejected as being unpatentable over Lafontaine, Ishiwara and Hussein, and further in view of US Patent 6,063,101 (Jacobsen et al.). Claims 13-14 were rejected as being unpatentable over Lafontaine, Ishiwara, Hussein, and further in view of US Patent 4,497,721 (Ginsburg).

In view of the foregoing comments, each of the outstanding rejections is respectfully traversed and reconsideration is requested.

Claim I is directed to a device to treat tissue including an outer tube, an inner tube disposed at least partially within the outer tube and including a guidewire lumen, a supply lumen and a return lumen, and a dual balloon. The duel balloon includes an inner balloon and an outer balloon, the inner balloon coupled to the inner tube at a proximal end and at a distal end, the outer balloon coupled to the inner tube at a distal end and to the outer tube at a proximal end. A first interior volume, defined between the outer balloon and the inner balloon, is in fluid communication with an inlet in the volume between the outer tube and the inner tube, and at least two radially extending tabs, extending from the inner tube, are disposed around a circumference of the inner tube to substantially center the inner tube within the dual balloon. Working fluid, input into a second interior volume, defined between the inner tube and the inner balloon, passes the radially extending tabs, and is not unduly impeded by the radially extending tabs.

The Final Action again takes the position that Lafontaine teaches all of the limitations of the claim except (1) a lumen to fill the volume between the balloons, and (2) spacers for maintaining position of elements". The Action then relies upon the alleged teachings of Ishiwara to arrive at limitation (1), and upon the alleged teachings of Hussein to arrive at limitation (2).

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In response to Applicant's previous arguments, the Final Action simply states that "the arguments relating to the radially tabs not persuasive as the spacers of Hussein et al. for relative positioning of apparatus parts is interpreted as an alternative to the claimed tabs".

Applicants submit that the "response to arguments" set out in the Final Action <u>completely</u> fails to address many of the <u>arguments previously submitted</u> by Applicant.

Specifically, as previously submitted, but not addressed in the Final Action, Applicants again submit that reference numeral 42 of Lafontaine is a 'chamber' – not a "balloon" this renders the proposed combination of teachings from Hussein moot, as Lafontaine teaches away from such a modification/combination.

As specifically recited in Lafontaine, the "chamber 42" of Lafontaine is "sized such that coolant entering the chamber from the coolant intake will evaporate in the chamber prior to exiting through the exhaust lumen" (col. 6, lines 15-17). Lafontaine further notes that "chamber 42 can be made from polyimide" (col. 3, lines 26-27).

Lafontaine clearly does not teach or suggest that <u>chamber 42 is a balloon</u> - element "14" of Lafontaine is a 'balloon', but element "42" is very specifically defined (and distinguished from "14"), to be a "chamber".

As described at col. 4, lines 22-30, "balloon 14 is dilated by forcing fluid into balloon 14 through inflation lumen 30 with pump 18...[c]oolant is then released into chamber 42 from a pressurized container or pump...".

For at least the foregoing reasons, Applicants respectfully submit that Lafontaine does not even teach or suggest a 'dual *balloon*''.

Since "chamber 42" of Lafontaine is not a "balloon", there would be no reason for one of ordinary skill in the art to even consider modifying the "chamber" to include tab members (or, what the Action calls, "spacers") extending from inner tube 32 (i.e., unless the 'chamber' is collapsible, why would such 'spacers' be necessary (or at all 'obvious' in light of the alleged teachings of Hussein) between tube 32 and chamber 42?).

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In addition, the Final Action relies upon Hussein as providing a teaching (acknowledged to be missing from both Lafontaine and Ishiwara) of a dual balloon catheter with spacers. Applicants again submit that Hussein is directed to a 'dual balloon catheter' in which two balloons are <u>spaced apart from one another along an elongated tubular structure</u>, defining an occluded segment or operating region therebetween (and not an 'inner' balloon and a 'outer' balloon). As noted at col. 7, lines 46-50 of Hussein, "the first balloon 234 is in fluid communication with a conduit defining the first fluid passageway 242... [and] [l]ikewise the second fluid passageway 244, defined by a conduit within inner tube 224, is for the expansion and collapse of the second balloon 236". Elongated spacer member 308 and 310 of Hussein are provided "on a carrier collar 298" – and are located between the carrier collar 298 and the inside wall surface of outer tube 220 (it is respectfully noted that this argument was also previously presented by Applicants in the response filed on December 3, 2007, but not addressed in the Final Action).

Therefore, it is again respectfully submitted that Hussein does not teach or suggest. Applicants claimed "radially extending tabs, <u>extending from an inner tube</u>, disposed around a circumference of the inner tube to substantially center the inner tube within the dual balloon" – and even if Hussein did provide such teaching (which again, it does not) — Lafontaine teaches away from such a modification, as Lafontaine's device has a chamber (rather than a balloon).

The Final Action, states that KSR "acknowledges the combination of existing features of analogous art as a natural progression within the existing threshold of a skilled artesian". Applicants submit that the proposed combination/modification (1) fails to even teach each of the recited elements as explained above, and (2) teaches away from the proposed modification. Therefore, the rejection does not fall into the KSR statement and is not a 'natural progression' as proposed.

For all of the foregoing reasons, independent Claim 1 is believed to be patentable over any permissible combination of the teachings of Lafontaine, Ishiwara, Hussein, Ginsburg and Jacobson, and reconsideration is requested.

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Dependent Claims 2-4 and 6-14 are believed to be clearly patentable for all of the reasons indicated above with respect to Claim 1, and even further distinguish over the cited references by reciting additional limitations.

Since the Applicants have fully responded to the Office Action, it is respectfully submitted that in regard to the above remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, request is made that the Examiner telephone the Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,

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